SEP 2 0 2001

510K Summary of Safety and Effectiveness

K012033

1. Sponsor Name

   Seedling Enterprises, LLC
   150 California Street
   Newton, MA 02458

2. Device Name

Proprietary Name:	Multifunction Endoscopic Instrument
Common/Usual Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories Class II by the General and Plastic Surgery Panel (21 CFR 878.4400) Product Code GEI.

3. Identification of Predicate or Legally Marketed Device

   The Multifunction Endoscopic Instrument is substantially equivalent in intended use and/or function to the following predicate devices:

- Everest Evershears Bipolar Scissors K 000496, manufactured by Everest Medical
- Circon Tripolar Forceps 510(k) number unknown, believed to be legally marketed under K884306, manufactured by Circon Corporation
- Clearglide Bipolar Device K 003587, manufactured by Ethicon, Inc.
- Bipolar Trigger Flex Electrode K003126, manufactured by ellman international inc
- Select-Sutter Micro-Bipolar Forceps K992760, manufactured by Select Sutter GmbH

4. Device Description

The Multifunction Endoscopic Instrument is a single patient use device, which is a combination scissors and bipolar coagulator-grasper. It is intended for use in conjunction with presently employed 5-10mm trocar cannulae. The instrument grasping and cutting functions are operated easily using one hand. The device is indicated for use in a variety of open and minimally invasive procedures. It is designed to facilitate grasping, mobilization, dissection, coagulation and transection of tissue.

The grasping and cutting functions of the distal end are accomplished by employing three elements.

- A central stationary member serves as both a scissors blade and a forceps jaw.
- A separate scissors blade and a forceps jaw are attached to the stationary member such that they can be independently pivoted to open and close thereby performing the cutting and grasping functions.
- The pivoting scissors blade and forceps jaw are connected to the handle and actuated via linkages.

5. Intended Use

The MEI is a laparoscopic and endoscopic, bipolar, electrosurgical device intended for grasping, dissecting, coagulating and transecting tissue in laparoscopic and open procedures.

The types of surgery indicated are:

General surgery
Laparoscopic procedures
Endoscopic procedures
Laryngeal coagulation
Orthopedic coagulation
Thorascopic coagulation
Neurosurgical coagulation
Gynecological coagulation, (except for use in female sterilization)
Ear, Nose and Throat coagulation

6. Comparison of Technological Characteristics

The Multifunction Endoscopic Instrument is substantially equivalent to the predicate devices listed, which provide the same or similar functions. All of the devices are bipolar scissors or graspers that permit the coagulation of soft tissue through the use of bipolar energy. All of the devices use sharp objects (scissors or knives) to permit the surgeon to cut the desiccated tissues. All are connected to the same or similar electrosurgical generators and use similar power ranges for operation.

The technological characteristics are the same as the predicates in that they are all electrosurgical devices that use bipolar electrical energy to provide coagulation powered by electrosurgical generators, and provide cutting with either a knife or a scissors. They are also similar in construction in that they have a handle, shaft and end effectors (working end). The working ends of the predicate devices are comprised of grasping or scissors jaws with the electrode surfaces, and embedded knives or scissors. The working end of the MEI is comprised of grasper jaws with the electrode surfaces, and scissor blades.

The intended use, statement of indications and technological and performance characteristics of the Multifunction Endoscopic Instrument support the concept of substantial equivalence.

7. Performance Testing

The Multifunction Endoscopic Instrument complies with the following voluntary standards:

- ANSI/AAMI HF18-1993 Electrosurgical Devices
- IEC 60601-1-2 Medical Electrical Equipment - General Requirements for Safety
- IEC 601-2-18 Medical Electrical Equipment - Part 2: Particular Requirements for safety of Endoscopic Equipment
- IEC 6060 1-2-2 Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Seedling Enterprises, LLC
c/o Ms. Debbie Iampietro
QRC Consulting Associates
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K012033
Trade/Device Name: Multifunction Endoscopic Instrument
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 27, 2001
Received: June 29, 2001

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Lisa Walker, RS

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012033

Device Name: Seedling Enterprises Multifunction Endoscopic Instrument

Indications For Use:

The MEI is a laparoscopic and endoscopic, bipolar, electrosurgical device intended for grasping, dissecting, coagulating and transecting tissue in laparoscopic and open procedures.

The types of surgery indicated are:

General surgery
Laparoscopic procedures
Endoscopic procedures
Laryngeal coagulation
Orthopedic coagulation
Thorascopic coagulation
Neurosurgical coagulation
Gynecological coagulation, (except for use in female sterilization)
Ear, Nose and Throat coagulation

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012033